#### FINAL STATEMENT OF REASONS

The information contained in the Initial Statement of Reasons (ISR) at the time of Public Notice remains unchanged with the exception of the following modifications.

**SECTION 30373(a).** (ISR, pages 7-9) The proposed regulation as originally noticed to the public, would have maintained existing language pertaining to the transportation of radioactive material outside the confines of a person's facility unless they were in compliance with specified federal provisions. The ISR, pages 8 and 9, stated that 10 CFR 71.0(c) and 71.3 were not being incorporated in section 30373(a)(1) because they were already addressed in section 30373(a). However, in response to comments from the U.S. Nuclear Regulatory Commission (NRC) indicating that this was incorrect, the Department changed the regulation by replacing existing language with language essentially identical to 10 CFR 71.0(c) and 71.3.

**SECTION 30373(a)(1).** (ISR, pages 8 – 11) The proposed regulation as originally noticed to the public, would have excluded 10 CFR 71.105(b) through (d) from being incorporated by reference. Page 10 of the ISR indicates that the essential objective of 10 CFR 71.105(b) is the same as that of §71.103(b), which is proposed to be incorporated and thus, not necessary to adopt this provision again. Also, page 10 of the ISR incorrectly stated that the compatibility category for 10 CFR 71.105(c) and (d) is [D]. However, in response to comments from the NRC to the contrary, and that 71.105(b), (c) and (d), originally proposed to not be incorporated, needed to be adopted to meet the designated compatibility categories, the Department changed the regulation by deleting those provisions listed as not being incorporated by reference resulting in fully incorporating 10 CFR 71.105 by reference.

**ISR**, page 10: The bulleted item " $\S\S71.107 - 71.125$ : NRC??? ." contains punctuation errors and should read as " $\S\S71.107 - 71.125$ : NRC."

**SECTION 30373(a).** (ISR, pages 7-8) Section 30373(a) refers to 10 CFR 71 "and Appendix A (January 1, 2007)." To ensure clarity the reference is amended to read "and Appendix A (as of January 1, 2007)."

**SECTION 30373(a)(4).** (ISR, pages 15 – 16) As originally proposed, subsection (a)(4) states that "When the term "licensed material" is used within the material incorporated by this section, it shall mean the same as defined in title 10, Code of Federal Regulations, part 20 section 20.1003 incorporated by reference in section 30253." Licensed material as defined in 10 CFR 20.1003 means any radioactive material including source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the Commission."

However, existing section 30253(a)(5) modifies the term's definition as found in 10 CFR 20.1003 as follows:

The definition of the term "Licensed material" in 10 CFR 20, section 20.1003 is modified to mean any radioactive material including source material, special nuclear

material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the NRC, or by any other Agreement State or by any state that has been either provisionally or finally designated as a Licensing State by the Conference of Radiation Control program Directors, Inc. With respect to dose limits and reporting requirements, the term "Licensed material" is to be construed broadly in context to include any source of ionizing radiation subject to the requirements of this regulation.

Thus, it is unclear as to which definition section 30373(a)(4) refers to; namely, the definition in 10 CFR 20 or the definition as modified by section 30253(a)(5). The Department's intent is that the term for purposes of section 30373 be defined as:

"Any radioactive material including source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the NRC, or by any other Agreement State or by any state that has been either provisionally or finally designated as a Licensing State by the Conference of Radiation Control program Directors, Inc."

That definition is verbatim to section 30253(a)(5) except that it does not include the second sentence, which states "With respect to dose limits and reporting requirements, the term "Licensed material" is to be construed broadly in context to include any source of ionizing radiation subject to the requirements of this regulation." Because 10 CFR 20 specifies dose limits and reporting requirements for personnel, the second sentence of section 30253(a)(5) clarifies that the Department applies those same dose and reporting standards to personnel who use other sources of radiation such as radiation-producing (X-ray) machines.

Section 30373 incorporates standards that apply to packages containing radioactive materials to ensure that the amount of radiation measured on the outside of the package is limited to a specific level and identified. It does not apply to personnel or use of X-ray machines. If the proposal was modified to identify the definition found in section 30253(a)(5), it could create confusion because of the second sentence that broadens the application of 10 CFR 20. Therefore, the proposal is amended to insert into proposed section 30373(a)(4) the applicable portion of the definition found in section 30253(a)(5) as follows:

"Any radioactive material including source material, special nuclear material, or byproduct material received, possessed, used, transferred or disposed of under a general or specific license issued by the NRC, or by any other Agreement State or by any state that has been either provisionally or finally designated as a Licensing State by the Conference of Radiation Control program Directors, Inc."

As discussed in the Initial Statement of Reasons, an Agreement State is any state that has entered into an agreement with NRC pursuant to the Atomic Energy Act of 1954, as amended, by which the NRC discontinues its regulatory authority over certain radioactive materials, giving it to the state. Currently, there are 38 Agreement States. Thus, the modified definition recognizes licensees from other agreement states, other than California, that have equivalent regulatory structures and implements Legislative policy to "Promote an orderly regulatory pattern within the State, among the states, and between the federal government and the State, and facilitate intergovernmental co-operation with respect to use

and regulation of sources of ionizing radiation to the end that duplication of regulation may be minimized." (Health & Saf. Code, § 114970(b).)

In furtherance of that policy, licensees from states that are provisionally or finally designated as a Licensing State (as opposed to an Agreement State) by the Conference of Radiation Control Program Directors (CRCPD) are included in the modified definition. This maintains consistency with existing section 30225, which recognizes licensees from NRC, licensing states, and Agreement States.

The CRCPD consists of the program directors who oversee radiation control in each state and issues radioactive material licenses, recognized by the NRC and other state programs for operations that use radioactive material. Designation as a licensing state requires that the state have equivalent CRCPD requirements, a licensing program for the regulatory control of radioactive material, and final or provisional designation by the CRCPD. Those states that have received such designation are called Licensing States. The CRCPD licensing state concept is a peer and state acknowledgement that a state is able to protect the citizenry from exposure to naturally occurring or accelerator-produced radiation. Licensing states include: Arizona, Colorado, Florida, Georgia, Illinois, Louisiana, Maryland, Mississippi, North Dakota, Oregon, Rhode Island, Tennessee, Texas, Utah, and Washington.

Clarifying that the term Licensed Material recognizes CRCPD-licensing states will benefit California businesses because it will permit them to receive reciprocal licenses from other states and reduce regulatory duplication as it relates to transportation of radioactive material. Many state programs grant reciprocal recognition to licensed individuals or entities from a licensing state but require those individuals or entities, which are from a non-licensing state, to obtain a radioactive materials license issued by that state. If the proposal does not recognize individuals or entities from licensing states, some CRCPD licensing states could refuse to grant California businesses the reciprocal recognition which would allow them to transport material in those states. Also, some states that are both agreement states and licensing states may not recognize California licenses because California does not recognize licensing states' licenses and some states that are only licensing states will not recognize California businesses. This forces California businesses to obtain a separate license from that state, increasing operational costs for California businesses wishing to work or transport material in a licensing state. Thus, by recognizing the CRCPD licensing state designation, California businesses will be able to compete in more states than they presently do.

**Incorporation by Reference:** Federal documents incorporated by reference in section 30373(a) and (a)(5) contain extensive tables, graphics, definitions, and provisions for safe packaging and transportation of radioactive material making it cumbersome, duly expensive and impractical to publish the documents in the California Code of Regulations. Further, the documents are readily available from federal sources as identified in second Note to section 30373.

### **Documents Relied Upon**

In accordance with Health and Safety Code section 114820(c), the Department obtained the Department of the California Highway Patrol's concurrence with the proposed changes to section 30100(f).

## <u>SUMMARY AND RESPONSE TO COMMENTS RECEIVED DURING THE INITIAL NOTICE</u> PERIOD OF AUGUST 26, 2008 THROUGH OCTOBER 24, 2008.

This regulation (DPH-07-008) was made available to the public from August 26, 2008 and ended at 5:00 p.m. on October 24, 2008. A request for a public hearing was not received and, thus, no public hearing was held. The written proceeding produced four comments from the NRC.

**Comments 1 & 2:** The NRC stated that the proposal did not meet the compatibility categories pertaining to title 10, Code of Federal Regulations, Part 71, section 71.0(c) (10 CFR 71.0(c)) and 10 CFR 71.3. The designated compatibility category for sections 71.0(c) and 71.3 is [B] meaning the Department is required to adopt essentially identical regulations unless they have been adopted in some other regulation.

**Response:** The Department agrees with the comments. Section 30373(a) was amended by adding language that meets the NRC's designated compatibility category of [B] for sections 71.0(c) and 71.3.

**Comments 3 & 4:** The NRC stated that the proposal did not meet the compatibility categories pertaining to 10 CFR 71.105. The ISR incorrectly stated on page 10 that the compatibility categories for 10 CFR 71.105(c) and (d) are category [D]. The correct category is compatibility category C.

**Response:** The Department agrees with the comments. Section 30373(a)(1) was amended by deleting provisions that were proposed to not be incorporated. The result is that 10 CFR 71.105 is fully incorporated by reference.

# COMMENTS RECEIVED DURING THE PERIOD THE MODIFIED TEXT WAS AVAILABLE TO THE PUBLIC.

The Department has complied with the requirements of Section 44 of Title 1 of the California Code of Regulations and the date upon which the notice and text were mailed was September 25, 2008. The public availability period began September 29, 2008 and ended October 14, 2008. An additional availability period was conducted; the date upon which the notice and text were mailed was January 30, 2009. This second public availability period began January 31, 2009 and ended February 17, 2009. The Department did not receive any comments on the modified text during either availability period.

#### **ALTERNATIVES DETERMINATION**

The Department has determined that, because the radiation control program must maintain compatibility with the regulations of the United States Atomic Energy Commission, the predecessor to the United States Nuclear Regulatory Commission (Health & Saf. Code, § 115230), and according to the agreement, the state is to use its "best efforts to maintain continuing compatibility between its program and the program of the [United States Atomic Energy] Commission for the regulation of like materials..." (Health & Saf. Code, § 115235, art. V) no alternative considered by the Department would be more effective in carrying out the purpose for which the regulation is proposed or would be as effective and less burdensome to affected private persons than the proposed regulation.

### **IMPOSITION OF LOCAL MANDATE**

The proposed regulations do not impose a mandate on local agencies or school districts.